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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/609,192 | 06/27/2003 | Ruoying Tan | 529702000100 | 7607 |

25226 7590 05/18/2006

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| EXAMINER |
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CHEU, CHANGHWA J

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| ART UNIT | PAPER NUMBER |
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1641

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/609,192

Applicant(s)

TAN ET AL.

Examiner

Jacob Cheu

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) 16-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 15 is/are allowed.
- 6) ☒ Claim(s) 1-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>1/16/04; 10/18/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group I, claims 1-15, in the reply filed on 3/31/2006 is acknowledged.

Applicant argues that a search for art describing methods for identifying a receptor will inevitably also encompass art describing related methods for identifying ligands, methods for identifying particular ligands and receptors, as well as methods determining binding activity between ligand and receptor. Applicant's arguments have been considered but are not persuasive. Because these inventions are distinct and have acquired separate status in the art as shown by their different classification, recognized divergent subject matter and because the search required for each invention is not substantially coextensive with the search required for the remaining invention, restriction for examination purposes as indicated is proper. Please note that the classifications in the restriction are illustrative only and do not represent all the classes and subclasses which must be searched for each invention; nor is the search limited to issued US patents, but rather includes published foreign patents and applications as well as literature search.

The Restriction Requirement is still deemed proper and is therefore made **FINAL**.

Accordingly, claims 1-15 are under examination. Claims 16-64 are withdrawn from further consideration.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claim 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, step (a), the term “threshold reporter enzyme molecule” is vague and indefinite. It is not clear what “threshold” applicant refers to. The term “threshold” does not denote any particular meaning for the recited assay with respect to the detection and analyzing. Applicant needs to clarify.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claim 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Flanagan et al. (US 5795734).

Flanagan et al. teach a method of identifying ligand and/or receptor interaction in a cellular system. Flanagan et al. teach fusing a known ligand covalently linked to a reporter enzyme where the enzyme can metabolize a suitable substrate and generating detectable signal when the ligand bind to a receptor from a sample having said receptor (Col. 4, line 36-45; Col. 5, line 55-67; Col. 6, line 58-68).

With respect to claim 2, Flanagan et al. teach washing away the uncomplex molecules from the receptor-ligand complex (Col. 38, line 52-67).

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With respect to claim 3-4, the assay taught by Flanagan et al. is a cellular expressing receptor assay. Supra.

With respect to claim 5, Flanagan et al. teach using fluorescence as detection signal (Col. 7, line 1-5).

With respect to claim 6-11, the ligand is a polypeptide (e.g. cellular surface receptor protein) which can be soluble or insoluble (Col. 42, line 60-68).

6. Claim 1-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Michnick et al. (US 20030108869).

Michnick et al. teach an assay for analyzing protein-protein interaction in a cellular system. William et al. teach fusing a first interacting domain, i.e. ligand, with a reporter enzyme, and a second interacting domain with a second reporter molecule, and contacting with a sample containing the receptor where the interaction of the receptor from the sample and the ligand cause the reporter enzyme to metabolize a suitable substrate and generating a detectable signal thereof (See Section 0019 -0021)

With respect to claim 2, Michnick et al. teach washing away the uncomplex molecules from the receptor-ligand complex (See example IV).

With respect to claim 3-4, the assay taught by Michnick et al. is a cellular expressing receptor assay. Supra.

With respect to claim 5, Michnick et al. teach using fluorescence as detection signal (See Section 0002 and 0031).

With respect to claim 6-11, the ligand is a polypeptide which can be soluble or insoluble .supra.

With respect to claim 12-15, Michnick et al. teach using CCF2 and nitrocefin as the substrate for beta-lactamase (See Section 0002).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claim 12-13, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flanagan et al. in view of Moore et al. (Annal. Biochem. 1997, Vol. 247, page 203-209- applicant submitted on 1/16/2004 # 15).

Flanagan et al. reference teaches using various enzymatic report genes, including galactosidase, alkaline phosphatase (Col. 7, line 1-15). However, William et al. does not explicitly teach use of beta-lactamase as the detection system.

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Moore et al. teach using beta-lactamase as the detection system for analyzing protein-protein interaction. This method provides advantages over the conventional enzymatic reporter, including 1. background free for gene expression; 2. variety of substrates can be synthesized by beta-lactamase; 3. can be continuously monitored without destruction of the cells; 4. the enzymes are extremely versatile so that it can fused to other proteins and retain activity (See Abstract).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Flanagan et al. with the beta-lactamase system as taught by Moore et al. in order to facilitate assay efficiency.

With respect to claim 15, Moore et al. teach using nitrocefin as the substrate (See page 205, left column, Method for beta-lactamase assay).

Conclusion

10. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

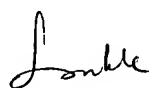
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu
Examiner
Art Unit 1641



May 4, 2006


LONG V. LE 05/12/06
SUPERVISORY PATENT EXAMINER
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